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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,238	06/04/2001	Jens Chr. Jensenius	09011-002003	6910

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

874,238

Applicant(s)

JENSENUS et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/27/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 18-23, 26, 37, 40-43 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 18-19, 22-23, 26, 40 is/are rejected.
- ☒ Claim(s) 20-21, 37, 41-43 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

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Amendment of 10/27/03 has been entered. Claims 18-23, 26, 37 and 40-43 are pending and under examination.

Applicant's amendment and urgings have overcome previously stated rejections under 112, first (new matter) and second paragraphs. The previously stated 112, first paragraph (enablement) rejection is maintained.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As previously noted, the method of claim 26 fails to enable a quantitative assay of "MASP-2 activity".

Applicant has urged that page 39, line 11 to page 40, line 11 describe an assay of MASP-2 activity in which MASP-2 is complexed with MBL (mannan binding lectin). This argument is unconvincing because, while MBL may bind the MASP-2 in a manner that does not diminish the enzymatic activity of MASP-2, one cannot extrapolate to assays in which MASP-2 is complexed with antibodies thereto. Since antibodies, in general can have unpredictable effects upon the activity of an antigenic enzyme (some antibodies can inhibit, some may even activate), the binding of an antibody to an enzymatic antigen merely allows one to quantitate the amount of the antigenic protein present (in active or inactive form) and not the enzymatic activity of the protein. Claims are not enabled, unless they are limited to use of a particular antibody that does not

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alter enzyme activity of MASP-2, when the antibody is complexed therewith. But it is not clear if applicant has disclosed any such antibodies.

The prior art rejection of record has not been overcome.

Claims 18-19, 22-23 and 40 are rejected under 35 U.S.C. 102(a) as being anticipated by Thiel et al (nature, 386,606,1997).

Applicant has attempted to overcome by submitting disclaiming statements from listed authors who are not inventors (Vorup-Jensen, Schwaeble, Laursen, Poulson, Willis, Eggleton, Hansen, Holmskon, and Reid).

The arguments presented with the amendment urge that these statements indicate that authors who are listed as inventors (Thiel and Jensenius) provided a Chicken antibody that reacts with MASP-2 (first para. of disclaiming statements headed "Discovery of MASP-2) and thus are the only authors who contributed to the instant invention that pertains to antibodies against MASP-2 and uses thereof.

The examiner finds this argument unconvincing. Examiner takes the chicken antibody referred to in the "Discovery of MASP-2" statements as being the same as that referred to in Thiel et al, at page 506, col.2. This antibody was raised against a "bovine lectin preparation" which is not defined in the reference. It is not clear from the record that this "bovine lectin preparation" is the same as an "antigen comprising a mannan binding lectin associated serine protease-2" as required by instant claim 18. Further even if it were established that these two antigen compositions were the same, it is not clear as to what other components may have been in the "bovine lectin preparation" which would have also induced the formation of antibodies that would also be present in

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the chicken antibody preparation. As such the chicken antibody preparation provided by Thiel and Jensenius does not meet the "specifically binds" limitation of instant claims 19 and 23.

Since the examiner understands the disclosures of Thiel et al, of the instant specification, and of para. 3 of the Jensenius 1.132 declaration as teaching that MASP-2 protein complexes with a mannose-binding lectin (MBL), the examiner considers that the above noted chicken antibody, raised against a "bovine lectin preparation" most certainly was raised against an impure preparation of lectins and various proteins associated therewith. Thus the examiner reasonably doubts that the chicken antibody provided by Thiel and Jensenius had the "specifically binding" property of instant claims 19 and 23. It is considered therefore that there was no provision of any antibody that "specifically binds" MASP-2 until, at least, the authors had the antibody raised against the N-terminal and/or c-terminal peptides of MASP-2 (page 507, col.1).

In order to obtain an antibody against the N-terminal peptide, the authors needed to know the N-terminal sequence of MASP-2. This was obtained by the author Willis ("Discovery of MASP-2", second para.), who thus provided a necessary inventive contribution.

Additionally to state claim 40 one would need to know SEQ ID NO:2, the amino acid sequence of MASP-2. From the "Discovery of MASP-2" statements (para.4-7), it appears that all authors who were involved in obtaining the cDNA and full mRNA sequences must have provided an inventive contribution to claim 40. the examiner takes these to be Vorup-Jensen, Reid, Eggleton, Schwaeble, Sim, and Stover.

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Finally, with respect to the "Discovery of MASP-2" statements provided by various authors, these have no probative value because they are not presented as declarations and there is no statement under section 1001 of 18 USC.

Applicant has also provided 1.132 declarations by Thiel and by Jensenius to allege the non-inventive contribution of the author Stover, who is not a listed inventor. These declarations indicate that the instant inventive entity provided the chicken antibody, while Stover was involved in obtaining the full length cDNA sequence. As the examiner has indicated supra, this sequence is necessary to arrive at SEQ ID NO: 2 recited in claim 40. Stover therefore provided an inventive contribution.

Applicant's urgings filed on 10/27/03 have been considered but are unconvincing.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is

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571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00 a.m to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd

February 26, 2004

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644